



Drug Enforcement Administration

[Docket No. DEA-953]

Bulk Manufacturer of Controlled Substances Application: Benuvia Therapeutics Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Benuvia Therapeutics Inc., has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on November 16, 2021, Benuvia Therapeutics Inc., 2700 Oakmont Drive, Round Rock, Texas 78665, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Tetrahydrocannabinols	7370	I
3,4-Methylenedioxyamphetamine	7400	I
3,4-Methylenedioxymethamphetamine	7405	I
5-Methoxy-N,N-dimethyltryptamine	7431	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
5-Methoxy-N,N-diisopropyltryptamine	7439	I

The company plans to bulk manufacture the listed controlled substances for the internal use intermediates or for sale to its customers. The company plans to manufacture the above-listed controlled substances in bulk to produce finished dosage forms and conduct research to develop new drug products and for clinical studies. In reference to drug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture this drug as a synthetic. No other activities for these drug codes are authorized for this registration.

Matthew J. Strait,

Deputy Assistant Administrator.

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